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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/31/2003

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 10/31/2003

251

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,623

Applicant(s)

CHEROK ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 and 54-59 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 and 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14-21, 29-45, 54-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant contends Mulhauser lacks a peripheral barrier that inhibits the formation of adhesions (claim 1) or a peripheral edge adapted to inhibit the formation of adhesions thereto (claims 29,37,54) because Mulhauser does not specifically disclose the ring inhibited adhesions. The Examiner disagrees. Mulhauser teaches the ring comprising silicone (lines 60-65 of col. 4), teaches tissue ingrowth only through the mesh fabric (lines 31-36 of col. 2), and that silicone does not promote tissue ingrowth (lines lines 51-59 of col. 4 and lines 32-37 of col. 5). Furthermore the figures clearly show a solid ring lacking interstices and a mesh repair fabric having interstices for tissue ingrowth. Therefore it would be apparent to one of ordinary skill in the art that tissue ingrowth would only occur through the mesh fabric.

Examiner also disagrees with regard to Applicant's contention that the entire thickness of the outer margin is not resistant to formation of adhesions. The figures show the entire thickness of the ring as a continuous structure and describe heat melting as a method to produce such structure. Therefore it would have been obvious to one of ordinary skill in the art to thoroughly heat melt the entire thickness to produce what is shown in the figures.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7,14-17,20,29-35,37-44,54,58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser et al. US PN 5,766,246.

Mulhauser et al. teaches in figures 2a-2b and 4a-4b and line 38 of col. 3 through line 56 of col. 5 an implantable prosthesis for repairing tissue or muscle wall defects comprising layer of polypropylene repair fabric (12), peripheral barrier (14) having an outer margin that has been melted and resolidified (see lines 64-65 of col. 4), and sutures for attaching the layers together. Mulhauser et al. teaches that during the melting a depression is formed implying a tapered shape. The peripheral barrier (14) may be considered a peripheral barrier (at the perimeter edge), a barrier layer (top or bottom of 14), as well as a reinforced bite region (see lines 65 of col. 4 through line 5 of col. 5).

The embodiment of figure 2a-2b does not expressly disclose a barrier layer that covers the entire first surface of the layer of repair fabric. However, the embodiment of figure 4a-4b teaches an additional barrier layer covering the entire surface of the repair fabric in order to prevent undesirable adhesions with nearby organs. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the embodiment in figures 2a-2b by adding the barrier layer of figures 4a-4b in order to prevent undesirable adhesions with nearby organs.

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4. Claims 18,19,45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser et al. US PN 5,766,246 as applied to claims 1,16, 37, and 44 above, and in further view of Sharber et al. US PN 6,075,180.

Mulhauser et al. teaches in figures 2a-2b and 4a-4b and line 38 of col. 3 through line 56 of col. 5 an implantable prosthesis for repairing tissue or muscle wall defects meeting the structural limitations of claims 18,19,45 as described above, but lacks the express disclosure of the suture being made of PTFE or other adhesion resistant material. Sharber et al. teaches in lines 54-67 of col. 1 the well known use of PTFE for implantable sutures because of PTFE's low reactivity in the human body.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the prosthesis disclosed by Mulhauser et al. by using PTFE material for the sutures because of PTFE's low reactivity in the human body.

5. Claims 21,36,55-57,59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser et al. US PN 5,766,246 as applied to claims 1,20,29,35,54,58 above, and in further view of Gianturco US PN 5,258,000.

Mulhauser et al. teaches in figures 2a-2b and 4a-4b and line 38 of col. 3 through line 56 of col. 5 an implantable prosthesis for repairing tissue or muscle wall defects meeting the structural limitations of claims 21,36,55-57,59 as described above, but lacks the express disclosure of the barrier layer being formed from ePTFE and the plurality of stitches being disposed inward of the outer peripheral edge. Gianturco teaches in lines 34 of col. 4 through line 43 of col. 5 and figures 3-4 an implantable

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prosthesis for repairing tissue or muscle wall defects comprising a barrier layer 16 and repair fabric layer 13, wherein the barrier layer is made of ePTFE to prevent tissue ingrowth and sutures (17) are located inward of the outer peripheral edge for securely connecting the fabric layers.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the prosthesis disclosed by Mulhauser et al. by using ePTFE material for the barrier layer and sutures located inward of the outer peripheral edge in order to prevent tissue ingrowth and securely connect the fabric and barrier layers.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WPM

WHM
October 28, 2003

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CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700